REMARKS

The Amendments

The solvate terms are removed from the claims to address the 35 U.S.C. §112 issue. Support for the new claims is found in the disclosure, for example, see page 17, lines 2-3, and original claims 10 and 11.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Restriction Requirement

Applicants submit that the method of making and method of use claims withdrawn pursuant to the restriction requirement (presumably also including new claims 15 and 16) should be subject to rejoinder upon allowance of the elected compound/composition claims; see, e.g., In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995); In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996); and the Commissioner's comments thereon in 1184 TMOG 86, March 26, 1996. Thus, the method claims are retained in the application.

The Objection to the Specification

As stated in the Office action, 37 C.F.R. §1.77(b) merely provides suggested guidelines as a preferred layout for the specification. Applicants are not required to follow this suggestion and choose not to do so here. The current specification meets all the requirements for a proper application. Thus, the objection should be withdrawn.

The Rejection under 35 U.S.C. §112, first paragraph

The rejection of claims 1-6 and 9 under 35 U.S.C. §112, first paragraph, for alleged lack of enablement, is rendered moot by the removal of the "solvate" terms from the claims.

The Rejection under 35 U.S.C. §103

The rejection of claims 1-4 and 9 under 35 U.S.C. §103 as being obvious over Cheng (*J.Org.Chem.*, 1958) (or further in view of Skipper, *Cancer Research*, vol. 17, pp. 579-596 (1957)) is respectfully traversed.

Applicants maintain their previous arguments, which are repeated below for completeness of the record, and address the counter-arguments made in the Final office action as follows.

The Final Office action fails to take into account the significant impact of the In re Stemniski, 170 USPQ 343 (CCPA 1971), case law and accompanying patent practice into account. Applicants pointed out in their last reply that – even if the compounds in the reference are considered adjacent homologs – it would not be obvious to modify them because the reference discloses no utility for the compounds alleged to be adjacent homologs. The Final Office action merely addresses the In re Lalu case and urges that the reference compounds are not taught merely as intermediates. Applicants disagree on this point but it is of no consequence, because the Stemniski case, which is not addressed in the action, is directly on point to the current facts whether or not the compounds are merely intermediates. As the court rhetorically asked in Stemniski, at 347:

> "Where the prior art reference neither discloses nor suggests a utility for certain described compounds, why should it be said that a reference makes obvious to one of ordinary skill in the art an isomer, homolog or analog of related structure, when that mythical, but intensely practical, person knows of no 'practical' reason to make the reference compounds, much less any structurally related compounds?"

See also MPEP §2144.08(II)(A)(4)(d), supporting this same point of law in examining practice and citing Stemniski for this point. Stemniski and the PTO examining practice following it is directly on point because Cheng clearly teaches no activity and no utility for the 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine compounds of their formula VI (i.e., for the compounds alleged to be adjacent homologs).

The Final Office action points to footnote 10 of Cheng and the Skipper reference cited there as supporting that Cheng does disclose that the 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine compounds have activity and utility. The footnote and the Skipper reference, however, do not support this position. Skipper tested the compounds that Cheng called 6-alkylpyrazolo-[3,4-d]pyrimidines of Cheng's formula XV which have an amino group at the 4-

position and some other compounds which were found to have activity, see Table 2 of Skipper. However, none of these compounds tested were the compounds alleged to be the adjacent homologs to applicants' compounds. These, 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine compounds alleged to be the adjacent homologs were tested but they "failed" to have activity. See Table 3 of Skipper including the heading to the table noting the failure of any activity and the compounds 71-73 tested as being within the failed group. Skipper acknowledges from the data the activity only for the 4-amino compounds at page 592, last paragraph (bottom right). It is pointed out there that one non-4-amino compound showed weak activity (see compound 20, Table 2, page 583). But this compound is not one of the compounds alleged to be an adjacent homolog. The compounds alleged to be the adjacent homologs here were tested but were clearly found to have no activity. Thus, there is no teaching of any utility therefore and no reason for one of ordinary skill in the art to modify them.

Cheng discloses a synthesis method for the eventual preparation of – what they call in the reference – 6-alkylpyrazolo-[3,4-d]pyrimidines. The compounds that Cheng calls 6-alkylpyrazolo-[3,4-d]pyrimidines are the compounds of the formula XV which have an amino group at the 4-position. See the formula XV in the diagram on page 193. It is evident that Cheng uses the 6-alkylpyrazolo-[3,4-d]pyrimidine term to refer to these compounds in distinction to Cheng's compounds of formula VI because Cheng uses the distinct term 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine for these compounds. Hence, the discussion of any possible physiological activity at page 193, bottom left-side column, in Cheng refers to the compounds of formula XV not the compounds of formula VI in Cheng. Note that in this paragraph the only specific compound mentioned as having an activity is a 4-dimethylamino substituted compound.

As noted in the Office action, Cheng discloses 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine compounds in Table II which differ from applicants' compounds at least because either: 1) the R2 group of Cheng is methyl and not ethyl or higher, and/or 2) the R1 group of Cheng, when a phenyl group, is not substituted phenyl. In both cases, the closest compounds of Cheng could be considered as adjacent homologs. However, such structural similarity, alone, does not support a prima facie case for obviousness. Particularly, in the case where the reference discloses no utility for the compounds that require modification there is no basis to make even a

small structural change to the compounds; see, e.g., In re Stemniski and the MPEP cite, discussed above. Similarly, in the case where the reference discloses such compounds only as intermediates, there is no basis to make even a small structural change to the compounds; see, e.g., In re Lalu, 74 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984).

In the instant case, Cheng is primarily directed to a synthesis method to provide compounds. Cheng provides only a brief and abstract discussion of possible activity of compounds in the paragraph at page 193, bottom left-side column. This discussion does not set forth any actual utility for the compounds discussed there. In any event, it should be clear that – even if this discussion did adequately describe a utility – it does not pertain to the compounds disclosed in Cheng which are most similar to the claimed compounds. There is no basis to tie this discussion in Cheng with the 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine compounds disclosed in Cheng's formula VI and Table II. To the contrary, the only compound which Cheng identifies as having some activity (i.e., for inhibiting Neurospora crassa) is a compound having a 4-amino group like those described in Cheng's formula XV and Table III.

For the above reasons, it is urged that the record fails to provide a sufficient reason for one of ordinary skill in the art to modify the Cheng compounds in the manner necessary to arrive at the claimed invention. The 6-alkyl-4-hydroxy-pyrazolo-[3,4-d]pyrimidine compounds of Cheng, particulary the 17th and 19th species listed in Table II on page 195, are not disclosed for having any activity or utility. Further, it appears that they are taught only as intermediates. In either event, there is no reason for one of ordinary skill in the art to make even minor modifications to them.

Accordingly, it is urged that the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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